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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,777	09/07/2006	Karl Groke	23304	2869

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EXAMINER	
STONE, CHRISTOPHER R	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
03/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,777	GROKE ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER R. STONE	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 18-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Finality of the Office Action, mailed October 16, 2008, is hereby withdrawn.

Applicants' arguments, filed January 9, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1-15 and 18-22 are currently pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is drawn to the therapeutic agent as according to claim 1, wherein the ratio of N-acetyl-seleno-methionine is 100:1 to 20000:1. However it is unclear what other component this ratio is relative to, so it is unclear what compositions this claim intends to encompass.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 and 18-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Groke et al (US 5,006,551) in view of Millis et al (Nutrition and Cancer, 31(1), 49-55, 1998), Menter et al (Cancer Epidemiology, Biomarkers and Prevention, Vol. 9, p. 1171-1182, 2000) and Bommarius et al (Tetrahedron: Assemetry, 8(19), p. 3197-3200, 1997).

Claims 1-15 and 18-22 are drawn to a composition comprising alpha-ketoglutaric acid, 5-hydroxymethylfurfural, N-acetyl-seleno-methionine and N-acetyl-L-methionine, a method of preparing said composition and a method of using said composition in the treatment of cancer.

Groke et al (US 5,006,551) teaches an aqueous composition for intravenous, oral or rectal administration composition comprising 5-20 g/L alpha-ketoglutaric acid, 1-3 g/L 5-hydroxymethylfurfural, 20-100 g/L glucose, 60-160 mmol/L sodium ion, and 15-40mmol/L potassium ion at a pH of 4-6 (column 1 line 54 to column 2 lines 42 and claim 11). Groke et al teaches that the composition may comprise alpha-ketoglutaric acid in the form of its monosodium or monopotassium salt and further comprising a taste improving disaccharide (column 2, line 66 to column 3, line 2 and column 4, lines 21-28). Groke et al teaches that the composition may be prepared by dissolving alpha-ketoglutaric acid above room temperature in distilled deaerated water and then adding glucose and akalis other than ammonia or amines and adjusting the pH to above 4 (4.9) and then adding the 5-hydroxymethylfurfural (column 6, example 2). Groke et al teaches that the composition may be prepared as a solid dosage form, including tablets and granules by adjusting the pH to 4-6 partly using alpha-ketoglutaric acid in the form of its monosodium of potassium salt and then adding extenders, disaccharides and then adding 5-hydroxymethylfurfural (column 3, lines 43-46 and column 4, lines 3-40). Groke et al further teaches a method of treating malignant cancers, including breast cancer, comprising administering intravenously said composition (claims 1, 4 and 11). Groke et al does not teach the composition further comprising N-acetyl-seleno-methionine and N-acetyl-L-methionine.

Millis et al teaches that N-acetyl-L-methionine is useful in the treatment of cancer (abstract).

Menter et al teaches that selenomethionine is useful in the treatment of cancer (abstract).

Bommarius et al teaches the use of the non-proteinogenic amino acid N-acetyl-seleno-methionine in therapeutic applications where selenomethionine is efficacious (p. 3197, first paragraph, compound 1-3c and p. 3198, second to last paragraph).

Therefore it would have been obvious to add N-acetyl-seleno-methionine and N-acetyl-L-methionine to the composition of Groke et al since N-acetyl-L-methionine was known to be useful in the treatment of cancer and N-acetyl-seleno-methionine was known to useful in therapeutic applications where selenomethionine is efficacious and selenomethionine was known to be useful in the treatment of cancer as well. Applicant is reminded of In re Kerkhoven which affirmed that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) Groke et al Millis et al, Menter et al, and Bommarius et al does not explicitly teach the claimed amounts and ratios of N-acetyl-seleno-methionine and N-acetyl-L-methionine. However it is obvious from the above teachings that Groke et al expressly contemplates variation in the composition component amounts and ratios and specifically acknowledges that such a matter was well within the skill of the artisan at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan. Factors that would have

been taken into consideration when making such a determination would have included, but not have been limited to, the age, weight, sex, diet and medical condition of the patient, severity of the disease, route of administration, pharmacological considerations, e.g., activity, efficacy, pharmacokinetics and toxicology profiles. Thus, the amounts and ratios of composition components that would have actually been employed would have been expected to vary widely and, in the absence of evidence to the contrary, would not have been inconsistent with that which is presently claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 18-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,006,551 in view of Millis et al (Nutrition and Cancer, 31(1), 49-55, 1998), Menter et al (Cancer Epidemiology, Biomarkers and Prevention, Vol. 9, p. 1171-1182, 2000) and Bommarius et al (Tetrahedron: Assemetry, 8(19), p. 3197-3200, 1997).

Claims 1-12 of U.S. Patent No. 5,006,551 are drawn to composition comprising 5-20 g/L alpha-ketoglutaric acid, 1-3 g/L 5-hydroxymethylfurfural, 20-100 g/L glucose, 60-160 mmol/L sodium ion, and 15-40mmol/L potassium ion at a pH of 4-6 for oral or intravenous administration and a method of using said composition for the treatment of cancers, including breast cancer. The composition of claims 1-12 of U.S. Patent No. 5,006,551 does not further comprise N-acetyl-seleno-methionine and N-acetyl-L-methionine.

Millis et al teaches that N-acetyl-L-methionine is useful in the treatment of cancer (abstract).

Menter et al teaches that selenomethionine is useful in the treatment of cancer (abstract).

Bommarius et al teaches the use of the non-proteinogenic amino acid N-acetyl-seleno-methionine in therapeutic applications where selenomethionine is efficacious (p. 3197, first paragraph, compound 1-3c and p. 3198, second to last paragraph).

Therefore it would have been obvious to add N-acetyl-seleno-methionine and N-acetyl-L-methionine to the composition of Groke et al since N-acetyl-L-methionine was known to be useful in the treatment of cancer and N-acetyl-seleno-methionine was

known to useful in therapeutic applications where selenomethionine is efficacious and selenomethionine was known to be useful in the treatment of cancer as well. Applicant is reminded of In re Kerkhoven which affirmed that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) Groke et al Millis et al, Menter et al, and Bommarius et al does not explicitly teach the claimed amounts and ratios of N-acetyl-seleno-methionine and N-acetyl-L-methionine. However it is obvious from the above teachings that Groke et al expressly contemplates variation in the composition component amounts and ratios and specifically acknowledges that such a matter was well within the skill of the artisan at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan. Factors that would have been taken into consideration when making such a determination would have included, but not have been limited to, the age, weight, sex, diet and medical condition of the patient, severity of the disease, route of administration, pharmacological considerations, e.g., activity, efficacy, pharmacokinetics and toxicology profiles. Thus, the amounts and ratios of composition components that would have actually been employed would have been expected to vary widely and, in the absence of evidence to the contrary, would not have been inconsistent with that which is presently claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

26March2009
CRS

/Patricia A. Duffy/
Primary Examiner, Art Unit 1645